

## REMARKS / ARGUMENTS

### 1. The Amendments to the Claims

Before this Amendment, claims 47 and 69 were pending. Upon entry of the present amendments, claims 47 and 69 will be pending and under active consideration.

Claim 47 and 69 have been amended to more particularly point out and distinctly claim the subject matter that the Applicant regards as his invention. The Applicant expressly reserves all rights to prosecute claims drawn to any subject matter removed by claim cancellation or by claim amendment made herein in a subsequent continuation application. No new matter is added by these amendments, and they are believed to place the claims in condition for allowance. The subject matter of the amended claims is fully supported in the specification and original claims as filed.

Claim 47 has been amended, as suggested by the Examiner, to recite the limitation "an isolated recombinant DNA." Support for amended claim 47 is found *inter alia*, at page 4, line 12 to page 8, line 25; page 9, lines 6-27, and page 10, line 19 to page 16, line 24 of the specification.

Claim 69 has been amended, as suggested by the Examiner, to recite the limitation "an isolated recombinant DNA." Support for amended claim 69 is found *inter alia*, at page 4, line 12 to page 8, line 25; page 9, lines 6-27, and page 10, line 19 to page 16, line 24 of the specification.

### 2. Claim Rejections

#### a. Examiner's Rejection Under 35 U.S.C. § 101 Should Be Withdrawn

At page 2 of the Office Action, claims 47 and 69 are rejected under 35 U.S.C. § 101 as being directed to non-statutory subject matter. The Examiner states that claim 47 encompasses "recombinant DNA from any transgenic organism, the scope of which encompasses a human being, which is non-statutory subject matter. As such, the recitation of the limitation "isolated" would be remedial. See 1077 O.G. 24, April 21, 1987."

As suggested by the Examiner, the Applicant has amended claim 47 to recite the limitation "an isolated recombinant DNA."

The Examiner has not expressly indicated the non-statutory subject matter, if any, that claim 69 encompasses. Claim 69 recites a "vector capable of expressing a recombinant DNA

comprising the recombinant DNA inserted into the vector such that a recombinant protein is expressed when the vector is provided in an appropriate host wherein the recombinant DNA is selected from the group consisting of . . . ." In order to be as fully responsive as possible, the Applicant has amended claim 69 to recite a vector capable of expressing [[a]] an isolated recombinant DNA comprising the isolated recombinant DNA inserted into the vector such that a recombinant protein is expressed when the vector is provided in an appropriate host wherein the isolated recombinant DNA is selected from the group consisting of . . . ."

It is respectfully submitted that the rejection under 35 U.S.C. § 101 is thus overcome. Reconsideration and withdrawal of the rejection of claims 47 and 69 are therefore respectfully requested.

**b. Examiner's Rejection Under 35 U.S.C. § 102(b) Should Be Withdrawn**

At pages 2-3 of the Office Action, claims 47 and 69 were rejected under 35 U.S.C. § 102(b), as being anticipated by Lewis *et al.* (1994, Sequence, organization, and evolution of the A+T region of *Drosophila melanogaster* mitochondrial DNA. *Mol. Biol. Evol.* 11: 523-538). The Applicant respectfully traverses the rejection.

**The Legal Standard.** For a rejection based on anticipation under 35 U.S.C. § 102, the Examiner must show "that all of the elements and limitations of the claim are found within a single prior art reference." *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1576 (Fed. Cir. 1991). A finding of anticipation is only proper in case of a "single prior art disclosure of all elements of a claimed invention arranged as in the claim." *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983).

The level of disclosure required for a reference under 35 U.S.C. § 102 (b) was pronounced by the court in *In re Sasse*, 207 USPQ 107, 111 (CCPA 1980):

... the proper test of a description in a publication as a bar to a patent as the clause is used in section 102 (b) requires a determination of whether one skilled in the art to which the invention pertains could take the description of the invention in the printed publication and combine it with his own knowledge of the particular art and from this combination *be put in possession of the*

*invention on which a patent is sought.* Unless this condition prevails, the description in the printed publication is inadequate as a statutory bar to patentability under section 102 (b).

*Id.* at 111 (citations omitted, emphasis in original).

Thus, a proper reference under Section 102 “must exhibit a substantial representation of the invention in such full, clear, and exact terms that one skilled in the art may make, construct and practice the invention without having to depend on either the patent or on his own inventive skills.” *Philips Electronics Corp. v. Thermal Industries, Inc.*, 171 USPQ 641, 644 (3<sup>d</sup> Cir. 1971). It “must describe the applicant’s claimed invention sufficiently to have placed a person of ordinary skill in the field of the invention in possession of it.” *In re Spada*, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990). A prior art reference anticipates a claim only if the reference discloses, either expressly or inherently, every limitation of the claim. *Rowe v. Dror*, 112 F.3d 473, 42 USPQ2d 1550 (Fed. Cir. 1997).

The Examiner maintains that Lewis *et al.* anticipates the claimed invention, specifically, that the amino acid translation of the sequences disclosed in Lewis *et al.* share homology with the amino acid sequences claimed in claims 47 and 69 (*i.e.*, SEQ ID NOs: 3, 5, 7, 9 and 11). The Applicant respectfully disagrees. The Applicant, Dr. Yung-Fu Chang, has performed an analysis of the sequences disclosed in Lewis *et al.* versus the sequences claimed in claims 47 and 69, and found that the translation of the Lewis *et al.* sequence does not share homology with any of the sequences claimed in claims 47 and 69.

To support the Applicant’s position that the sequences disclosed in Lewis *et al.* do not share homology with the claimed sequences, the Applicant submits herewith a Declaration Under 37 C.F.R. § 1.132. In the Declaration, Dr. Chang describes the routine methods that he used to conduct his analysis (BLAST analysis), and declares that he was unable to find any homology between the translation of the sequence disclosed by Lewis *et al.* and any portion of the amino acid sequences claimed in claims 47 and 69. He further declares that an ordinarily skilled artisan would not understand Lewis *et al.* as disclosing the sequences claimed in claims 47 and 69 or homologous sequences, and such a person could not have combined the Lewis *et al.* reference’s description of bases 14917 to 19517 of the *Drosophila melanogaster* mitochondrion genome with the artisan’s own knowledge to make the claimed invention.

Thus the Lewis *et al.* reference does not disclose each and every element of claims 47

and 69, nor would an ordinarily skilled artisan have been able to combine the Lewis *et al.* reference's description of bases 14917 to 19517 of the *Drosophila melanogaster* mitochondrion genome with his own knowledge to make the claimed invention. *See, e.g., Helifix Ltd. v. Blok-Lok, Ltd.*, 208 F.3d 1339, 54 USPQ2d 1299 (Fed. Cir. 2000). Therefore Lewis *et al.* does not anticipate these claims.

It is respectfully submitted that the rejection under 35 U.S.C. § 102 is thus overcome. Reconsideration and withdrawal of the rejection of claims 47 and 69 as being anticipated by Lewis *et al.* are therefore respectfully requested.

### CONCLUSION

In view of the foregoing amendments and remarks, the Applicant believes that the application is in good and proper condition for allowance. Early notification to that effect is earnestly solicited. If the Examiner feels that a telephone call would expedite the consideration of the application, the Examiner is invited to call the undersigned attorney at (315) 425-9000.

If there are any other fees due in connection with the filing of this Amendment or accompanying papers, please charge the fees to Marjama & Bilinski LLP's Deposit Account No. 50-0289. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to the Deposit Account.

Respectfully submitted,

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Enclosures